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UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Patent Interference 105,685 (RES)
Technology Center 1600

WYETH,
(Named inventors: Anthony F. Hadfield, Syed M. Shah,
James A. Provost, Aeri Park, Rex A. Shipplett,
Brenton W. Russell, and Beat T. Weber),
Patents 6,673,838 B2 and 7,291,347 B2,
Junior Party,

v.

SEPRACOR, INC.
(Named inventors: Thomas P. Jerussi, Chrisantha H. Senanayake,
and Nandkumar N. Bhongle)
Applications 10/720,134, 11/091,518 and 12/011,083,
Senior Party.

Before: RICHARD E. SCHAFER, JAMESON LEE, and
RICHARD TORCZON, *Administrative Patent Judges.*

JUDGMENT and RECOMMENDATION

Judgment

As part of a settlement agreement between Wyeth and Sepracor, Wyeth has become the owner of Sepracor's involved applications. As provided in 37 C.F.R. § 41.206, it is appropriate to enter judgment when the involved applications and patents become commonly owned.

The record of this interference shows that Sepracor was accorded a constructive reduction to practice date of April 6, 1999, for the subject matter of the three counts – Counts 5, 6 and 7. Paper 105. Wyeth's priority statement alleges August 30, 2000, as its earliest dates of conception and actual reduction to practice. Paper 22. Since Wyeth did not allege a date of invention earlier than the effective date accorded to Sepracor, we award judgment on priority against Patents 6,673,838 and 7,291,347 as to the subject matter of Counts 5, 6 and 7.

Recommendation

During the interference, certain prior art came to the attention of the Board. A single judge order (Paper 109) discussed the possibility that the involved claims were unpatentable under 35 U.S.C. §§ 102 or 103 in light of the prior art. Paper 109 is incorporated in and made part of this judgment. A copy is attached.

Pursuant to 37 C.F.R. § 1.127(c), we recommend that the patentability of the claims of Applications 10/720,134, 11/091,518 and 12/011,083 be considered in light of the prior art discussed in Paper 109.

ORDER

For the reasons stated, it is

ORDERED that judgment on priority as to the subject matter of Counts 5, 6 and 7 (Paper 108, pp. 2-4), is awarded against Patents 6,673,838 B2 and 7,291,347 B2;

FURTHER ORDERED that claims 1-3 (corresponding to Count 5), Claims 23-34 and 46 (corresponding to Count 7) of Patent 6,673,838 B2, and Claims 1-9 of Patent 7,291,347 B2 (corresponding to Count 6) shall be cancelled (35 U.S.C. § 135(a));

RECOMMENDED that the patentability of the claims of Applications 10/720,134, 11/091,518 and 12/011,083 be considered in light of the references discussed in Paper 109;

FURTHER ORDERED that a copy of this judgment be made of record in the files of Patents 6,673,838 B2 and 7,291,347 B2 and Applications 10/720,134, 11/091,518 and 12/011,083;

FURTHER ORDERED that if there is any settlement agreement or related documents which have not been filed, attention is directed to 35 U.S.C. § 135(c) and 37 C.F.R. § 41.205.

/Richard E. Schafer/
RICHARD E. SCHAFER
Administrative Patent Judge

/Jameson Lee/
JAMESON LEE
Administrative Patent Judge

/Richard Torczon/
RICHARD TORCZON
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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Paper 109
Entered: 1 February 2010

UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference 105,685 McK
Technology Center 1600

WYETH
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Senior Party.

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge.*

PATENTABILITY OF CLAIMS

A. Introduction

A merits panel of the Board has determined that certain Sepracor applications contain a written description of O-desmethylvenlafaxine succinate. *See* Paper 102, pages 23-41 entered concurrently herewith.

In connection with motions already filed, considered and decided, the following prior art came to the Board's attention:

Husbands	U.S. Patent 4,535,186 Ex 2028	13 Aug. 1985
Rudolph 1	U.S. Patent 5,916,923 Ex 1023	29 Jun. 1999
Rudolph 2	European Patent Application 0 639 374 A2 Ex 2029	22 February 1995

Husbands and Rudolph 2 are prior art vis-à-vis Sepracor and Wyeth under 35 U.S.C. § 102(b).

Rudolph 1 is prior art vis-à-vis Wyeth under 35 U.S.C. § 102(b).

Rudolph 1 is prior art vis-à-vis Sepracor under 35 U.S.C. § 102(e) having issued after Sepracor's effective filing date of 6 April 1999. Rudolph 1 is based on an application (08/368,521) filed 4 January 1995, an application which is said to be a "continuation" of an application (08/083,848) filed 28 June 1993.

The disclosures of Rudolph 1 and Rudolph 2 appear to be similar. In fact, Rudolph 2 claims priority based on Rudolph 1 (Ex 2029, cover page, item 30).

Based on evidence and arguments presented by the parties in connection with Sepracor's opposition (Paper 88) to Revised Wyeth Motion 2 (Paper 77), Sepracor takes the position that O-desmethylvenlafaxine succinate (ODMV succinate) is described in its various applications. The Board has agreed with Sepracor. If the Sepracor applications contain a written description of ODMV succinate, then it would appear that the three prior art references set out above also describe ODMV succinate. Under the circumstances, it would appear that both party's claims corresponding to Counts 5, 6, and 7 are unpatentable under 35 U.S.C. § 102 or 35 U.S.C. § 103.

B. Facts

Claim 60 of Sepracor application 10/720,134 claims:

> A compound which is O-desmethylvenlafaxine succinate.

Rudolph 2, in its background of the invention, states that the active ingredients of the Rudolph invention include

> (1-[2-(dimethylamino)-1-(4-methoxyphenyl) ethyl] cyclohexanol),

or therapeutically acceptable salts thereof, which are known generally as venlafaxine and its analogues. Ex 2029, page 3:3-5.

Venlafaxine is disclosed in U.S. Patent 4,535,186 (Husbands—Ex 2028) and had been previously reported to be useful as an antidepressant. Ex 2029, page 3:5-6.

Husbands (Ex 2028) is incorporated by reference into Rudolph 2. Ex 2029, page 3:7.

In Rudolph 2, venlafaxine should be understood to include (1) the free base and pharmaceutically acceptable salt forms of venlafaxine, (2) the racemate and its individual enantiomers, and (3) venlafaxine analogs, both as racemates and as their individual enantiomers. Ex 2029, page 3:7-10.

According to Rudolph 2, venlafaxine has been shown to be a potent inhibitor of monoamine *neurotransmitter* uptake, a mechanism associated with clinical antidepressant activity. Due to its novel structure, venlafaxine is said to have a mechanism of action unrelated to other available antidepressants. Ex 2029, page 3:11-14.

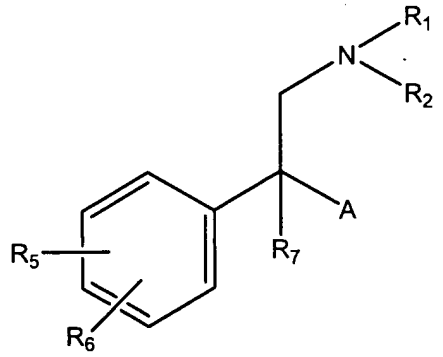
Rudolph states that it is believed that venlafaxine's mechanism of action is related to potent inhibition of the uptake of the monoamine neurotransmitters *serotonin* and *norepinephrine*. To a lesser degree, venlafaxine also is said to inhibit *dopamine* reuptake. Ex 2029, page 3:15-17. For additional discussion on

uptake of *serotonin*, *norepinephrine* and *dopamine*, *see*, *e.g.*, Ex 1053, page 50:13 through page 55:16 where on cross-examination Dr. Martin H. Teicher describes data in Table 3 of Muth, *Drug Development Research*, page 196 (1991) relating to uptake.

The Rudolph 2 invention is said to provide a method of treating, preventing, or controlling a variety of ailments, including obesity, panic disorder, post-traumatic stress disorder, late luteal phase dysphoric disorder (premenstrual syndrome), attention deficit disorders, with and without hyperactivity, Gilles de la Tourette syndrome, bulimia nervosa, generalized anxiety disorder or Shy Drager Syndrome in mammals, preferably in humans. Each of these disorders is said to exhibit a physiological basis for treatment by venlafaxine's ability to inhibit monoamine neurotransmitters. Ex 2029, page 3:28-34.

Rudolph 2 describes a "genus" of "compounds of this invention." Ex 2029, page 4:39 through page 5:44.

The "preferred [subgenus] compounds" have the formula:



where the various R and A moieties may be:

R_1 can be hydrogen or alkyl of 1 to 3 carbon atoms (one carbon atom would be methyl).

R_2 can be alkyl of 1 to 3 carbon atoms (one carbon atom would be methyl).

R_5 can be hydrogen.

R_6 can be hydroxyl (—OH).

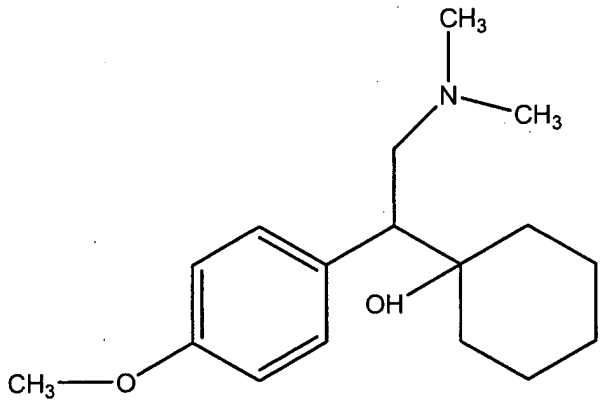
R_7 can be hydrogen.

A can be cyclohexanol when R_4 is hydrogen and n is 2 and there is no double bond in the formula shown at page 5:5.

This "broad" subgenus disclosure does not anticipate Sepracor claim 1 reproduced above.

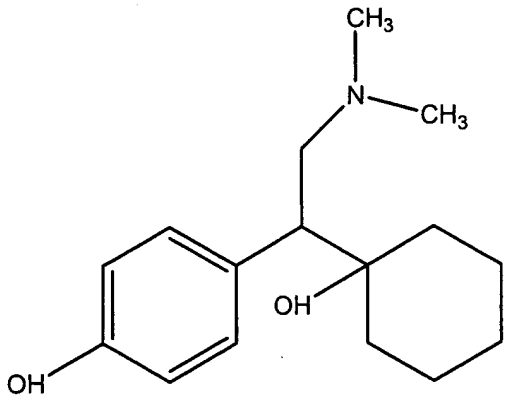
However, Rudolph 2 goes on to state that compounds "[o]f particular interest are the compounds 1-[(2-dimethylamino)-1-(*4-methoxy*phenyl)ethyl]cyclohexanol and 1-[(2-dimethylamino)-1-(*4-hydoxy*phenyl)ethyl]cyclohexanol and the enantiomers and pharmaceutically acceptable salts thereof.

The first compound is venlafaxine.



Venlafaxine is the "preferred compound" where R_5 is hydrogen and R_6 is *methoxy* [—O—CH_3] in the 4-position of the phenyl ring.

The second compound is O-desmethylvenlafaxine:



O-desmethylvenlafaxine (ODMV) does not "fit" within the "preferred [subgenus] compounds" because while R_5 can be hydroxyl [—OH], R_6 cannot be hydrogen. ODMV does "fit" within the broad genus described by Rudolph at page 4:45 through page 5:20 where R_5 can be hydroxyl and R_6 can be hydrogen. Ex 2029, page 5:19.

Nevertheless, it must be remembered that ODMV is a metabolite of venlafaxine. Ex 2029, page 3:17-18. According to Rudolph 2, ODMV is venlafaxine's major metabolite in humans—meaning that when venlafaxine is administered to humans it metabolizes into ODMV.

Rudolph 2 also describes acids which can be used to make pharmaceutically acceptable salts. Those acids can be inorganic or organic acids, including [1] hydrochloric, [2] hydrobromic, [3] fumaric, [4] maleic, [5] succinic, [6] sulfuric, [7] phosphoric, [8] tartaric, [9] acetic, [10] citric, [11] oxalic and similar acids. Ex 2029, page 5:54-57.

With respect to dosage, Rudolph 2 states (Ex 2029, page 6:20-44; italics added):

> Preferably the pharmaceutical composition is in unit dosage form, e.g. as tablets or capsules. In such form, the composition is sub-divided in unit doses containing appropriate quantities of the active ingredient;

the unit dosage forms can be packaged compositions, for example, packeted powders or vials or ampoules. The unit dosage form can be a capsule, cachet or tablet itself, or it can be the appropriate number of any of these in package form. The quantity of the active ingredient in *a unit dose* of composition may be varied or adjusted from 2 mg. or less to 50 mg. or more, according to the particular need and the activity of the active ingredient. The usual oral recommended dose of venlafaxine for humans may be between about 75 and about 200 mg/day and this dose may be administered in two or three divided doses, preferably with food if administered orally. A maximum recommended daily dose for humans would be about 375 mg, but it will be understood by one skilled in the art that dosage under this invention will be determined by the particular circumstances surrounding each case.

Claim 4 of Rudolph 2, as published, calls for the "use" of venlafaxine or a pharmaceutically acceptable salt thereof. Ex 2029, page 8:20-21.

Claim 5 of Rudolph 2, as published, calls for the "use" of ODMV or a pharmaceutically acceptable salt thereof. Ex 2029, page 8:23-24.

Claim 6 calls for the "use" of a daily dose from 50 mg/day to 375 mg/day. Ex 2029, page 8:26-27.

C. Discussion

What is good for the goose is good for the gander.

If Sepracor is correct that it is entitled to § 120 benefit in connection with Wyeth's § 135(b)(2) motion, then it would appear that Rudolph 2 anticipates Sepracor claim 1 reproduced above. Other Sepracor and Wyeth claims may also be unpatentable under § 102(b) over Rudolph. The claims which Sepracor sought

to have designated as not corresponding to Count 7 would appear to be unpatentable under § 103 over Rudolph for the same reason that those claims are unpatentable over the subject matter of Count 7. Sepracor has already had a full and fair opportunity to establish unobviousness, but failed to do so. If Sepracor claim 1, reproduced above, is unpatentable under § 102(b) (an issue to be looked into), then claims sought to be designated as not corresponding to Count 7 would be unpatentable under § 103 (an issue already resolved in this interference).

D. Priority

Wyeth does not allege a date earlier than the priority date accorded to Sepracor.

Accordingly, as acknowledged at oral argument by Wyeth, it cannot prevail on priority—at least on the current record.

On the other hand, if Sepracor and Wyeth claims are *not* unpatentable over Rudolph 2, then the Board might have to reevaluate whether Sepracor is entitled to its benefit date—in which case Wyeth might prevail on priority.

A decision on priority will be held in abeyance pending resolution of patentability.

E. Order

Upon consideration of the record, it is

ORDERED that a conference call is set for **17 February 2010** at **2:00 pm [1400 hours]** to discuss how patentability might be addressed in this interference.

105,685
(via electronic mail):

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